



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-20-200T; Docket No. CDC-2020-0063]**

**Proposed Data Collection Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS)

**ACTION:** Notice with comment period

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Mycoplasma genitalium Treatment Failure Registry." The purpose of the collection is to determine which second-line antibiotics are in use for M. genitalium treatment failure and

monitor antibiotic resistance patterns for treatment failure cases throughout the United States.

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2020-0063 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger,

Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

#### Proposed Project

Mycoplasma genitalium Treatment Failure Registry - New -  
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB  
Prevention (NCHHSTP), Centers for Disease Control and Prevention  
(CDC).

#### Background and Brief Description

The Centers for Disease Control and Prevention (CDC),  
Division of STD Prevention requests a three-year approval of an  
information collection request for the Mycoplasma genitalium

Treatment Failure Registry, which will entail use of a standardized Case Report Form.

The primary goal of this activity is to establish a registry to monitor cases of *Mycoplasma genitalium* (*M. genitalium*) treatment failure in the United States. The project objectives are as follows: 1) Using existing clinical data, describe demographic and behavioral factors among patients with documented *Mycoplasma genitalium* who fail current CDC-recommended treatment. 2) Using existing clinical data, describe antibiotic regimens utilized among patients with *Mycoplasma genitalium* treatment failure, including documentation of clinical and microbiologic cure. 3) Using existing laboratory specimens, monitor genetic mutations associated with macrolide or fluroquinolone antibiotic resistance. Data captured on the standardized Case Report Form will be analyzed to determine outcomes from usage of second-line antibiotic therapy for *M. genitalium*. These data may inform future CDC STD Treatment Guidelines.

There are an estimated 100 respondents (anticipated to report once per year) who will be clinicians in private and public health care settings. The data collection is necessary as there are no current national recommendations for patients who fail current CDC-recommended therapy for *M. genitalium*.

Each case report form is anticipated to take up to 60 minutes to complete.

This data collection provides CDC with information to determine which second-line treatments are most clinically effective, as well as determining antibiotic resistance patterns of *M. genitalium* throughout the US. There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection are 100 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Physician or Nurse Practitioner	M.genitalium Treatment Failure Registry Case Report Form	100	1	1	100

*Jeffrey M. Zirger,*  
Lead,  
Information Collection Review Office,  
Office of Scientific Integrity,  
Office of Science,  
Centers for Disease Control and Prevention.

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